DSJ1&2-PR Exh 525

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-op-45090	MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster

SUMMIT COUNTY AND CITY OF AKRON, OHIO PLAINTIFF'S SUPPLEMENTAL RESPONSES AND OBJECTIONS TO DISTRIBUTOR DEFENDANTS' INTERROGATORY NUMBERS 2, 3, 4, 8, 12, 14, 15, 16, 17, 23, 24, 27 & 29

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and the Case Management Order in *In re National Prescription Opiate Litigation*, No. 1:17-cv-2804 (Dkt. No. 232), the County of Summit, Ohio and the City of Akron, Ohio (collectively "Plaintiff") hereby responds to Distributor Defendants'[1] Interrogatory Nos. 2, 3, 4, 8, 12, 14, 15, 16, 17, 23, 24, 27 & 29 (the "Interrogatories" and, each individually, an "Interrogatory"), as follows:

OBJECTIONS

The following objections apply to each Interrogatory. To the extent that certain specific objections are cited in response to an individual Interrogatory, those specific objections are provided because they are applicable to that specific Interrogatory and are not a waiver of the other objections applicable to information falling within the scope of such Interrogatory.

1. Plaintiff objects to each Interrogatory to the extent they are overly broad, vague, unduly burdensome, seek information that is not relevant to any party's claim or defense, or seek

[1] The Distributor Defendants are AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation (collectively "Distributors").

Amended Responses and Objections to Distributor Defendants' Third Set of Interrogatories" dated August 13, 2018 (Distributor Interrogatory Nos. 16 & 17); and "Initial Responses and Objections to Manufacturer Defendants' Second Set of Interrogatories" dated July 5, 2018 (Manufacturer Interrogatory No. 27).

Interrogatory No. 23 (Re-Written):

Identify each Suspicious Order for Prescription Opioids that you contend was shipped to Your geographic area by any National Retail Pharmacy Defendant or Distributor Defendant during the Relevant Time Period. For each order, identify the date the order was shipped, the manufacturer, name, and amount of the medication that was shipped, the name of the defendant that shipped the order, and the name and location of the person or entity that placed the order. Furthermore, explain the criteria you used to identify these Suspicious Orders.

Response:

Plaintiff repeats and reasserts their prior objections and adopt their prior responses to this Interrogatory. Plaintiff reserves the right to supplement this answer through expert witnesses pursuant to the Scheduling Order entered by the Court. Plaintiff intends to disclose through expert testimony: (a) orders previously designated by each distributor as suspicious; (b) orders which should have been designated as suspicious using the system designed and operated by each distributor; and (c) orders which should have been designated as suspicious using a "common sense" approach.

Plaintiff incorporates by reference its "Responses to the Amended and Clarified Discovery Ruling 12 Supplemental Interrogatory Issued to Plaintiffs" dated January 25, 2019 (Pharmacy Interrogatory No. 7 and Distributor Interrogatory No. 23); "Responses to Supplemental Interrogatory Issued in Discovery Ruling 12 to Plaintiffs" dated January 11, 2019

(Pharmacy Interrogatory No. 7 and Distributor Interrogatory No. 23); "Supplemental Amended Responses and Objections to the Manufacturer Defendants' First Set of Interrogatories, Submitted Pursuant to Discover Ruling No. 13" dated December 31, 2018 (Manufacturer Interrogatory No. 6); "Supplemental Objections and Responses to Manufacturer Defendants' Interrogatory Nos. 27/28" dated December 21, 2018; "Fourth Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories" dated December 14, 2018 (Manufacturer Interrogatory Nos. 6 & 10); "Supplemental Responses & Objections to Reformulated Suspicious Order Interrogatory Served by Manufacturer Defendants" dated November 27, 2018 (Manufacturer Interrogatory No. 27); "Amended Responses and Objections to the Manufacturer Defendants' First Set of Interrogatories and the National Retail Pharmacy Defendants' First Set of Interrogatories" dated November 2, 2018 (Manufacturer Interrogatory No. 10 and Pharmacy Interrogatory Nos. 2 & 3); "Amended Responses and Objections to the National Retail Pharmacy Defendants First Set of Interrogatories and Distributor Defendants' Fourth Set of Interrogatories" dated October 31, 2018 (Distributor Interrogatory No. 23 and Pharmacy Interrogatory No. 7); "Responses and Objections to Distributor Defendants' Fourth Set of Interrogatories" dated August 31, 2018 (Distributor Interrogatory Nos. 23 & 29); "First Amended Responses and Objections to Distributor Defendants' Third Set of Interrogatories" dated August 13, 2018 (Distributor Interrogatory Nos. 16 & 17); and "Initial Responses and Objections to Manufacturer Defendants' Second Set of Interrogatories" dated July 5, 2018 (Manufacturer Interrogatory No. 27).

In addition, Plaintiff responds as follows:

This discovery request is a contention interrogatory. "Contention" interrogatories seek to clarify the basis for or scope of an adversary's legal claims. *Starcher v. Corr. Med. Sys., Inc.*, 144

F.3d 418, fn. 2 (6th Cir. 1998), aff'd sub nom. *Cunningham v. Hamilton Cty., Ohio*, 527 U.S. 198, 119 S. Ct. 1915, 144 L. Ed. 2d 184 (1999).

To be clear it is the position of the Plaintiff answering herein, that the answer to this contention interrogatory "does not limit [our] experts from using different criteria to identify suspicious orders, and therefore from concluding that there exist suspicious orders in addition to those identified [herein]." Discovery Ruling No. 7, p. 6.

Plaintiff objects to this Interrogatory to the extent that it seeks identification of suspicious orders shipped to pharmacies outside of their geographic answer. Discovery in the current phase of the MDL has been largely limited to the jurisdictions comprising the Track One cases and, in connection with the analogous Interrogatory posed by Distributor and Pharmacy Defendants, Special Master Cohen reformulated the Interrogatory to seek only identification of suspicious orders "shipped to Your geographic area." *See, e.g.*, Discovery Ruling No. 7, Dkt. 1051 at 5. Plaintiff contends that the same limitation should apply to the current interrogatory.

Plaintiff further objects to this interrogatory to the extent that responsive information is at least as available to Defendants as to Plaintiff. Indeed, information necessary to respond fully to this Interrogatory is more readily available to Defendants. Specifically, discovery to date has revealed that such information is readily available to Defendants from one or more of the following sources: chargeback data provided to Manufacturers by Distributors, data provided by Distributors pursuant to Fee For Service (FFS) Agreements with Manufacturers, EDI data, 867 data, and/or sophisticated prescriber/patient-level data Manufacturers obtained from data vendors like IMS as part of their sales/marketing strategies. Thus, Defendants had and currently have it within their ability to identify all transactions from the produced list that involve their own opioid products. Nevertheless, Plaintiff herein will provide Defendants with sufficient

information about the methodology by which they have identified suspicious orders to permit Defendants to duplicate the analysis with their own particular orders.

Although Defendants have objected to Plaintiff's prior responses to this Interrogatory as listing only transactions between distributors and pharmacies, Plaintiff contends that those are suspicious orders as to which Defendants had duties to report and to (attempt to) stop shipment. The duty under federal law to report suspicious orders is not limited to orders actually shipped by the Manufacturer. Indeed, upon recommending the denial of Manufacturer Defendants' Motion to Dismiss, the Court held that the text of 21 U.S.C. § 823 and 21 C.F.R. § 1301.74 are not so limiting as to exempt the Manufacturer Defendants from the requirement to identify and report orders beyond their direct customers – i.e. downstream orders. *See* Report & Recommendation, Dkt. 1025 at 74. Moreover, discovery has revealed that most distributor agreements between Manufacturers and Distributors expressly define the retail level customers (pharmacies) that receive shipments from the Distributor Defendants as "customers" of the Manufacturer, not the Distributor. They are therefore suspicious orders attributable to the Manufacturer of that product. Furthermore, although the Manufacturer Defendants have taken the position that they were not in a position to halt orders between Distributors and customers, discovery to date has revealed that Manufacturers were able (and sometimes threatened) to use their refusal to process chargebacks for sales between Distributors and customers identified as having placed suspicious orders to effectively terminate the processing of suspicious orders, and Plaintiff reserve its right to identify additional orders based on this information. Finally, although Manufacturers have taken the position that they could not halt orders between Distributors and customers, this position ignores the ability of Manufacturers to halt orders from Distributors whom they knew were filling

suspicious orders by customers, aloof which could have been deemed suspicious and for which Plaintiff reserves its right to identify additional orders based on this information.

Plaintiff contends each Manufacturer and Distributor Defendant, as a registrant, owes a duty under federal law and implementing regulations to maintain "effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, and industrial channels." 21 U.S.C.A. § 823(a)(1). This duty, which is identical to the duty applied to distributors pursuant to 21 U.S.C.A. § 823(b)(1), has been defined to include certain "security requirements" identified in 21 C.F.R. § 1301.72-1307.76 which the DEA has imposed on all registrants and deemed "necessary to prevent diversion," including:

> The "security requirement" at the heart of this case mandates that distributors "design and operate a system" to identify "suspicious orders of controlled substances" and report those orders to DEA (the Reporting Requirement). 21 C.F.R. § 1301.74(b). The Reporting Requirement is a relatively modest one: It requires only that a distributor provide basic information about certain orders to DEA, so that DEA "investigators in the field" can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out "potential illegal activity." Southwood Pharm., Inc., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007). Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement).

Masters Pharm., Inc. v. Drug Enf't Admin., 861 F.3d 206, 212–13 (D.C. Cir. 2017) (emphasis added); *see also* 21 C.F.R. §§ 1301.11, 1301.71, 1301.74.

Plaintiff contends that the Defendants failed to maintain effective controls against diversion by designing and operating a system to identify suspicious orders into Summit County between 1996 and the present, or if they implemented such a system, it was not legally compliant and/or followed in practice, in violation of federal law thereby causing and/or contributing to the

opioid epidemic. Specifically, the Defendants did not report suspicious orders that they were aware of and/or failed to stop shipments of suspicious orders.

Plaintiff contends it is facially evident that an unusually large and exponentially increasing volume of prescription opioids were shipped into Summit County, as evidenced by ARCOS data.

In order to determine which of the individual transactions is "suspicious" under federal law, the DEA would apply the system "designed and operated" by the registrant on a transaction-by-transaction basis. *See, e.g.*, *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017) (applying the SOM adopted by Masters Pharmaceutical). Consequently, Plaintiff has sought discovery from each Defendant of its Suspicious Order Monitoring System (SOMS) policies and procedures since January 1, 2006, as well as discovery of all orders identified as suspicious pursuant to these SOMS. Defendants have objected to these discovery requests and, to date, none have provided fully complete and transparent responses sufficient to allow Plaintiff to accurately apply each Defendants' own SOMS algorithm to their own transactional data. Despite repeated requests, Plaintiff does not have sufficient documents or data to identify each suspicious order that was or should have been detected by each Defendant. Thus, the answer to this contention interrogatory is premised upon the current status of the record which has the following limitations:

a. One or more the Defendants have yet to fully disclose transactional data for the relevant timeframe;
b. One or more of the Defendants have yet to fully disclose the "system" (or algorithm) utilized to detect suspicious orders for the relevant timeframe;
c. One or more of the Defendants have yet to fully disclose each suspicious order detected by the Defendants for the relevant timeframe;
d. One or more of the Defendants have yet to fully disclose the suspicious orders reported to the DEA for the relevant timeframe; and

> e. One or more of the Defendants have yet to fully disclose the due diligence performed for each suspicious order which was ultimately shipped for the relevant timeframe.

Defendants demand Plaintiff disclose which orders it contends are suspicious without a full evidentiary record of: their policies and procedures; transactional data, including the chargeback data, EDI data, FFS data, and IMS data which Defendants were in possession of the systems and/or algorithms used by the Defendants to detect suspicious orders; the orders each of the Defendants' systems detected as suspicious; the orders reported to the DEA as suspicious; the due diligence performed before shipping a suspicious order; and expert witness discovery and testimony.

In a good faith effort to meet their discovery obligations, Plaintiff takes note of the following instructive analysis from the *Masters* Court:

> More fundamentally, the key question in this case is not whether held orders qualified as "suspicious" under Masters' policies; the question is whether they qualified as "suspicious" under 21 C.F.R. § 1301.74(b). Thus, while Masters frames its challenge on this point in substantial-evidence terms, the relevant inquiry is more legal than factual: It asks how far the language of the regulation reaches. Undertaking that legal exercise, the Administrator reasonably determined that all held orders were "suspicious" within the meaning of the regulation. Section 1301.74(b) provides that "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." Apparently tracking that regulatory language, the Computer Program held an order if: (a) that order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months; (b) the pharmacy ordered a controlled medication more frequently in a 30-day period than it had in any of the previous six calendar months; or (c) the pharmacy's ordering pattern for a controlled medication deviated in some other notable way from its ordering pattern over the previous six months. As a matter of common sense and ordinary language, orders that deviate from a six-month trend are an "unusual" and not "normal" occurrence. It was therefore entirely reasonable for the Administrator to hold that orders held by the Computer Program met the regulatory definition of "suspicious orders" unless Masters' staff dispelled the suspicion.

Masters Pharm., Inc. v. Drug Enf't Admin., 861 F.3d 206, 216–17 (D.C. Cir. 2017) (internal citations omitted) (emphasis added).

Bellwether Plaintiffs have previously identified multiple suspicious orders based on one or more of the following criteria: (a) met the criteria ratified in *Masters Pharm., Inc. v. Drug Enf't Administration*, 861 F.3d 206, 216–17 (D.C. Cir. 2017);[6] (b) was shipped within thirty days of an order of the same national drug code ("NDC") that was deemed suspicious and reported to DEA; (c) included the same drug family ordered by the same customer in the same month from multiple distributors; (d) was in top 10% for percentage increases for the same drug family or for total orders for the month or year; and/or (e) was of excessive size for the drug family for a customer whose prescribing significantly exceeded other similar pharmacies in the jurisdictions. Depending on the particular methodology employed, Bellwether Plaintiffs identified somewhere between 52,554 (Method 1) and 875,055 (Method 3) suspicious orders shipped into Summit between January 1996 and May 2018.

For the purposes of responding to these premature contention interrogatories, Plaintiff has not attempted to identify every possible suspicious order, nor applied every reasonable method for identifying suspicious orders. Plaintiff reserves the right to supplement or amend this answer as expert discovery commences.

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[6] Method 1 ("Exceeding Threshold of Any of the Previous Six Months and Assuming Due Diligence"): All monthly order(s) exceeding the largest total order of any of the previous six months is considered suspicious. Method 1 assumes due diligence on the suspicious order(s), it is cleared and shipped.

Method 2 ("Exceeding Threshold of Initial 6 Months and Assuming No Due Diligence"): All monthly order(s) exceeding the largest order in any of the initial six months of the applicable dataset is considered suspicious. Method 2 assumes no due diligence on the suspicious order(s), but it is cleared and shipped. The threshold does not increase after the initial six months because each and every order shipped thereafter in excess of any of the initial six month threshold is unlawful.

Method 3 ("Previous 6 Months Threshold is Triggered and Assuming No Due Diligence"): Once an order(s) exceeds the largest order(s) in any of the previous six months of the applicable dataset all subsequent orders are considered suspicious. Method 3 assumes no due diligence on the suspicious order(s) and as a result, each and every order shipped thereafter to that individual buyer is unlawful.

ANSWER: In a good faith effort to meet its discovery obligations, consistent with the requirements set forth by Special Master Cohen in his Discovery Rulings 7 and 12, Plaintiff hereby identifies the orders identified in Bellwether Plaintiffs' prior responses as suspicious orders.

Further answering, Mallinckrodt has produced consolidated unusual order reports at MNK-T1_0007730452, MNK-T1_0007730468; MNK-T1_0001810733; MNK-T1_0002079926; and MNK-T1_ MNK-T1_0001810813. In addition, Mallinckrodt has produced peculiar order spreadsheets (*see* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 32 Ex. A); unusual order reports (*see* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 32 Ex. B); and DEA suspicious order reports (*see* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 32 Exs. C & D). Plaintiff contends that many of the orders identified in these documents were suspicious and were improperly shipped by Mallinckrodt.

Mallinckrodt has also identified 24 orders prior to 2009 that it determined were suspicious and were not shipped. *See* MNK-T1_0007026342, MNK-T1_000269049, MNK-T1_000301983, MNK-T1_0006805898, MNK-T1_0004268059, MNK-T1_0004267998, MNK-T1_000301986, MNK-T1_000277496, MNK-T1_000274675, MNK-T1_000269046, MNK-T1_000275736, MNK-T1_000275748, MNK-T1_000562325, MNK-T1_000259231, MNK-T1_0000259220, MNK-T1_0000475208, MNK-T1_0000475126, MNK-T1_0000296226, MNK-T1_0008590891, MNK-T1_0007202509, MNK-T1_0002363592, MNK-T1_0006442328, MNK-T1_0007730869, and MNK-T1_0007202115. In addition to these orders, Mallinckrodt has identified thousands of orders that have the same or similar identifying information as the above orders but were nevertheless shipped. *See* Mallinckrodt's Supplemental Responses and

Objections to Interrogatory No. 32 at 53 and MNK-T1_0008592409. Plaintiff contends that many of these orders were suspicious and were improperly shipped by Mallinckrodt.

Plaintiff has also identified numerous documents and obtained testimony demonstrating that Mallinckrodt failed to adequately review and scrutinize suspicious orders prior to shipping them, including the deposition transcripts, deposition exhibits and custodial files of: Karen Harper, Eileen Spaulding, John Gillies, Bill Ratliff, Victor Borelli, Steven Becker, Ginger Collier, Kate Muhlenkamp, Lisa Cardetti, James Rausch, Cathy Stewart, George Saffold, and Tiffany Rowley-Kilper. The custodial files for the above individuals also contain additional documents supporting Plaintiff's claims regarding the lack of adequate due diligence.

In addition, Mallinckrodt has identified the following prescribers and "other individuals" that it believes engaged in "inappropriate prescribing practices or other illegal acts concerning the diversion of Opioids into the illegal supply chain": Dr. Adolp Harper, Dr. Brian Heim, Dr. Ronald Celeste, Dr. Michael Tricaso, Dr. Gregory Gerber, Louis Eppinger, Patricia Arnold, Anthony H. Perry, Elizabeth Davis, James Byrge, Judy Barrows, Brittany Glass, Patricia Laughman, Adria Harper, and Tequilla Berry. *See* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 21 at 21. A review of Mallinckrodt's documents indicates that these individuals obtained Mallinckrodt products, and that many of these individuals were well known to Mallinckrodt prior to their arrests were on Mallinckrodt "target" lists of high-prescribing doctors that it actively solicited to prescribe their products. *See, e.g.*, MNK-T1_0002159629, MNK-T1_0002282670, MNK-T1_0004814570, MNK-T1_0002719188, MNK-T1_0007068789.

Plaintiff reserves the right to supplement or amend its response as expert discovery commences, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 24:

Identify all false and/or fraudulent information that You allege any Distributor Defendant supplied to the Drug Enforcement Administration about Suspicious Orders as alleged in Paragraph 859 of the Second Amended Complaint.

Response:

Plaintiff repeats and reasserts their prior objections and adopt their prior responses to this Interrogatory. Plaintiff objects to this Interrogatory to the extent the term "all false and/or fraudulent information" is vague and ambiguous and subject to varying interpretations. Plaintiff objects to this Interrogatory as unduly burdensome and not proportional to the needs of this case because it would be virtually, if not literally, impossible for Plaintiff to identify every/or "all false and/or fraudulent information" that Defendants "supplied to the Drug Enforcement Administration." Plaintiff is not privy to the Defendants' communications with the DEA. Plaintiff objects in that this Interrogatory seeks information uniquely in the possession of Defendants and/or third-parties. To the extent Plaintiff were able to identify all responsive information, Plaintiff objects that it is unduly burdensome and disproportionate to the needs of the case for Plaintiff to be asked to identify all false and/or fraudulent information that the Distributor Defendants supplied to the Drug Enforcement Administration ("DEA") about Suspicious Orders. This Interrogatory is contention discovery more appropriately answered once discovery is completed. See Fed. R. Civ. P. 33(a)(2).[7]

[7] Subject to and without waiving all objections, Plaintiff incorporates by reference its responses to Distributor Defendants' Interrogatory Nos. 23 & 29 dated January 25, 2019 and August 31, 2018; Manufacturer Defendants'

> [t]he postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse of Opana ER due to:
>
> - the short period of time represented
> - the overlap of prescriptions for both the original formulation of OPANA ER and reformulated OPANA ER during the first quarter of the reporting period
> - the continued availability of original OPANA ER throughout the reporting period
> - the possible misclassification of the original and reformulated products based on the similar appearance of the two products.
>
> ENDO-OR-CID-01174359.

In addition, thousands of video messages with false or misleading statements were disseminated by Purdue and others. By way of example, see:

ENDO-CHI_LIT-00037637
ENDO-CHI_LIT-00058655
ENDO-CHI_LIT-00334741
JAN00023015
PMT000328743
PMT000328849
PMT000328906
PURCHI-000526551
PURCHI-000822872

Plaintiff reserves the right to supplement or amend its response as expert discovery commences, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 29:

For each Suspicious Order that You contend was shipped into Your geographic area by a Distributor Defendant, identify how, if at all, the Prescription Opioids were used following the shipment, including what percentage of the Prescription Opioids were diverted, abused, used for legitimate medical purposes, used in some other manner, or destroyed, and if the Prescription

Opioids were diverted, abused, or otherwise used improperly, who was involved in such diversion, abuse, or other improper use.

Response:

Plaintiff repeats and reasserts their prior objections and adopt their prior responses to this Interrogatory. Plaintiff reserves the right to supplement this answer through expert witnesses pursuant to the Scheduling Order entered by the Court. Plaintiff intends to disclose through expert testimony: (a) orders previously designated by each distributor as suspicious; (b) orders which should have been designated as suspicious using the system designed and operated by each distributor; and (c) orders which should have been designated as suspicious using a "common sense" approach.

Plaintiff incorporates by reference its "Responses to the Amended and Clarified Discovery Ruling 12 Supplemental Interrogatory Issued to Plaintiffs" dated January 25, 2019 (Pharmacy Interrogatory No. 7 and Distributor Interrogatory No. 23); "Responses to Supplemental Interrogatory Issued in Discovery Ruling 12 to Plaintiffs" dated January 11, 2019 (Pharmacy Interrogatory No. 7 and Distributor Interrogatory No. 23); "Supplemental Amended Responses and Objections to the Manufacturer Defendants' First Set of Interrogatories, Submitted Pursuant to Discover Ruling No. 13" dated December 31, 2018 (Manufacturer Interrogatory No. 6); "Supplemental Objections and Responses to Manufacturer Defendants' Interrogatory Nos. 27/28" dated December 21, 2018; "Fourth Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories" dated December 14, 2018 (Manufacturer Interrogatory Nos. 6 & 10); "Supplemental Responses & Objections to Reformulated Suspicious Order Interrogatory Served by Manufacturer Defendants" dated November 27, 2018 (Manufacturer Interrogatory No. 27); "Amended Responses and Objections to the Manufacturer Defendants' First Set of Interrogatories and the National Retail Pharmacy

Defendants' First Set of Interrogatories" dated November 2, 2018 (Manufacturer Interrogatory No. 10 and Pharmacy Interrogatory Nos. 2 & 3); "Amended Responses and Objections to the National Retail Pharmacy Defendants First Set of Interrogatories and Distributor Defendants' Fourth Set of Interrogatories" dated October 31, 2018 (Distributor Interrogatory No. 23 and Pharmacy Interrogatory No. 7); "Responses and Objections to Distributor Defendants' Fourth Set of Interrogatories" dated August 31, 2018 (Distributor Interrogatory Nos. 23 & 29); "First Amended Responses and Objections to Distributor Defendants' Third Set of Interrogatories" dated August 13, 2018 (Distributor Interrogatory Nos. 16 & 17); and "Initial Responses and Objections to Manufacturer Defendants' Second Set of Interrogatories" dated July 5, 2018 (Manufacturer Interrogatory No. 27).

In addition, Plaintiff responds as follows:

This discovery request is a contention interrogatory. "Contention" interrogatories seek to clarify the basis for or scope of an adversary's legal claims. *Starcher v. Corr. Med. Sys., Inc.*, 144 F.3d 418, fn. 2 (6th Cir. 1998), aff'd sub nom. *Cunningham v. Hamilton Cty., Ohio*, 527 U.S. 198, 119 S. Ct. 1915, 144 L. Ed. 2d 184 (1999).

To be clear it is the position of the Plaintiff answering herein, that the answer to this contention interrogatory "does not limit [our] experts from using different criteria to identify suspicious orders, and therefore from concluding that there exist suspicious orders in addition to those identified [herein]." Discovery Ruling No. 7, p. 6.

Plaintiff objects to this Interrogatory to the extent that it seeks identification of suspicious orders shipped to pharmacies outside of their geographic answer. Discovery in the current phase of the MDL has been largely limited to the jurisdictions comprising the Track One cases and, in connection with the analogous Interrogatory posed by Distributor and Pharmacy Defendants, Special Master Cohen reformulated the Interrogatory to seek only identification of suspicious

orders "shipped to Your geographic area." *See, e.g.*, Discovery Ruling No. 7, Dkt. 1051 at 5. Plaintiff contends that the same limitation should apply to the current interrogatory.

Plaintiff further objects to this interrogatory to the extent that responsive information is at least as available to Defendants as to Plaintiff. Indeed, information necessary to respond fully to this Interrogatory is more readily available to Defendants. Specifically, discovery to date has revealed that such information is readily available to Defendants from one or more of the following sources: chargeback data provided to Manufacturers by Distributors, data provided by Distributors pursuant to Fee For Service (FFS) Agreements with Manufacturers, EDI data, 867 data, and/or sophisticated prescriber/patient-level data Manufacturers obtained from data vendors like IMS as part of their sales/marketing strategies. Thus, Defendants had and currently have it within their ability to identify all transactions from the produced list that involve their own opioid products. Nevertheless, Plaintiff herein will provide Defendants with sufficient information about the methodology by which they have identified suspicious orders to permit Defendants to duplicate the analysis with their own particular orders.

Although Defendants have objected to Plaintiff's prior responses to this Interrogatory as listing only transactions between distributors and pharmacies, Plaintiff contends that those are suspicious orders as to which Defendants had duties to report and to (attempt to) stop shipment. The duty under federal law to report suspicious orders is not limited to orders actually shipped by the Manufacturer. Indeed, upon recommending the denial of Manufacturer Defendants' Motion to Dismiss, the Court held that the text of 21 U.S.C. § 823 and 21 C.F.R. § 1301.74 are not so limiting as to exempt the Manufacturer Defendants from the requirement to identify and report orders beyond their direct customers – i.e. downstream orders. *See* Report & Recommendation, Dkt. 1025 at 74. Moreover, discovery has revealed that most distributor agreements between Manufacturers and Distributors expressly define the retail level customers (pharmacies) that

receive shipments from the Distributor Defendants as "customers" of the Manufacturer, not the Distributor. They are therefore suspicious orders attributable to the Manufacturer of that product. Furthermore, although the Manufacturer Defendants have taken the position that they were not in a position to halt orders between Distributors and customers, discovery to date has revealed that Manufacturers were able (and sometimes threatened) to use their refusal to process chargebacks for sales between Distributors and customers identified as having placed suspicious orders to effectively terminate the processing of suspicious orders, and Plaintiff reserve its right to identify additional orders based on this information. Finally, although Manufacturers have taken the position that they could not halt orders between Distributors and customers, this position ignores the ability of Manufacturers to halt orders from Distributors whom they knew were filling suspicious orders by customers, all of which could have been deemed suspicious and for which Plaintiff reserves its right to identify additional orders based on this information.

Plaintiff contends each Manufacturer and Distributor Defendant, as a registrant, owes a duty under federal law and implementing regulations to maintain "effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, and industrial channels." 21 U.S.C.A. § 823(a)(1). This duty, which is identical to the duty applied to distributors pursuant to 21 U.S.C.A. § 823(b)(1), has been defined to include certain "security requirements" identified in 21 C.F.R. § 1301.72-1307.76 which the DEA has imposed on all registrants and deemed "necessary to prevent diversion," including:

> The "security requirement" at the heart of this case mandates that distributors "design and operate a system" to identify "suspicious orders of controlled substances" and report those orders to DEA (the Reporting Requirement). 21 C.F.R. § 1301.74(b). The Reporting Requirement is a relatively modest one: It requires only that a distributor provide basic information about certain orders to DEA, so that DEA "investigators in the field" can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out

> "potential illegal activity." Southwood Pharm., Inc., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007). Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement).

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Plaintiff contends that the Defendants failed to maintain effective controls against diversion by designing and operating a system to identify suspicious orders into Summit County between 1996 and the present, or if they implemented such a system, it was not legally compliant and/or followed in practice, in violation of federal law thereby causing and/or contributing to the opioid epidemic. Specifically, the Defendants did not report suspicious orders that they were aware of and/or failed to stop shipments of suspicious orders.

Plaintiff contends it is facially evident that an unusually large and exponentially increasing volume of prescription opioids were shipped into Summit County, as evidenced by ARCOS data.

In order to determine which of the individual transactions is "suspicious" under federal law, the DEA would apply the system "designed and operated" by the registrant on a transaction-by-transaction basis. *See, e.g.*, *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017) (applying the SOM adopted by Masters Pharmaceutical). Consequently, Plaintiff has sought discovery from each Defendant of its Suspicious Order Monitoring System (SOMS) policies and procedures since January 1, 2006, as well as discovery of all orders identified as suspicious pursuant to these SOMS. Defendants have objected to these discovery requests and, to date, none have provided fully complete and transparent responses sufficient to allow Plaintiff to accurately apply each Defendants' own SOMS algorithm to their own transactional data.

Despite repeated requests, Plaintiff does not have sufficient documents or data to identify each suspicious order that was or should have been detected by each Defendant. Thus, the answer to this contention interrogatory is premised upon the current status of the record which has the following limitations:

> a. One or more the Defendants have yet to fully disclose transactional data for the relevant timeframe;
> b. One or more of the Defendants have yet to fully disclose the "system" (or algorithm) utilized to detect suspicious orders for the relevant timeframe;
> c. One or more of the Defendants have yet to fully disclose each suspicious order detected by the Defendants for the relevant timeframe;
> d. One or more of the Defendants have yet to fully disclose the suspicious orders reported to the DEA for the relevant timeframe; and
> e. One or more of the Defendants have yet to fully disclose the due diligence performed for each suspicious order which was ultimately shipped for the relevant timeframe.

Defendants demand Plaintiff disclose which orders it contends are suspicious without a full evidentiary record of: their policies and procedures; transactional data, including the chargeback data, EDI data, FFS data, and IMS data which Defendants were in possession of; the systems and/or algorithms used by the Defendants to detect suspicious orders; the orders each of the Defendants' systems detected as suspicious; the orders reported to the DEA as suspicious; the due diligence performed before shipping a suspicious order; and expert witness discovery and testimony.

In a good faith effort to meet their discovery obligations, Plaintiff takes note of the following instructive analysis from the *Masters* Court:

> More fundamentally, the key question in this case is not whether held orders qualified as "suspicious" under Masters' policies; the question is whether they qualified as "suspicious" under 21 C.F.R. § 1301.74(b). Thus, while Masters frames its challenge on this point in substantial-evidence terms, the relevant inquiry is more legal than factual: It asks how far the language of the regulation reaches. Undertaking that legal exercise, the Administrator reasonably determined that all held orders were "suspicious" within the meaning of the regulation. Section 1301.74(b) provides that "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual

> frequency." Apparently tracking that regulatory language, the Computer Program held an order if: (a) that order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months; (b) the pharmacy ordered a controlled medication more frequently in a 30-day period than it had in any of the previous six calendar months; or (c) the pharmacy's ordering pattern for a controlled medication deviated in some other notable way from its ordering pattern over the previous six months. As a matter of common sense and ordinary language, orders that deviate from a six-month trend are an "unusual" and not "normal" occurrence. It was therefore entirely reasonable for the Administrator to hold that orders held by the Computer Program met the regulatory definition of "suspicious orders" unless Masters' staff dispelled the suspicion.

Masters Pharm., Inc. v. Drug Enf't Admin., 861 F.3d 206, 216–17 (D.C. Cir. 2017) (internal citations omitted).

Bellwether Plaintiffs have previously identified multiple suspicious orders based on one or more of the following criteria: (a) met the criteria ratified in *Masters Pharm., Inc. v. Drug Enf't Administration*, 861 F.3d 206, 216–17 (D.C. Cir. 2017);[13] (b) was shipped within thirty days of an order of the same national drug code ("NDC") that was deemed suspicious and reported to DEA; (c) included the same drug family ordered by the same customer in the same month from multiple distributors; (d) was in top 10% for percentage increases for the same drug family or for total orders for the month or year; and/or (e) was of excessive size for the drug family for a customer whose prescribing significantly exceeded other similar pharmacies in the

[13] Method 1 ("Exceeding Threshold of Any of the Previous Six Months and Assuming Due Diligence"): All monthly order(s) exceeding the largest total order of any of the previous six months is considered suspicious. Method 1 assumes due diligence on the suspicious order(s), it is cleared and shipped.

Method 2 ("Exceeding Threshold of Initial 6 Months and Assuming No Due Diligence"): All monthly order(s) exceeding the largest order in any of the initial six months of the applicable dataset is considered suspicious. Method 2 assumes no due diligence on the suspicious order(s), but it is cleared and shipped. The threshold does not increase after the initial six months because each and every order shipped thereafter in excess of any of the initial six month threshold is unlawful.

Method 3 ("Previous 6 Months Threshold is Triggered and Assuming No Due Diligence"): Once an order(s) exceeds the largest order(s) in any of the previous six months of the applicable dataset all subsequent orders are considered suspicious. Method 3 assumes no due diligence on the suspicious order(s) and as a result, each and every order shipped thereafter to that individual buyer is unlawful.

jurisdictions. Depending on the particular methodology employed, Bellwether Plaintiffs identified somewhere between 52,554 (Method 1) and 875,055 (Method 3) suspicious orders shipped into Summit between January 1996 and May 2018.

For the purposes of responding to these premature contention interrogatories, Plaintiff has not attempted to identify every possible suspicious order, nor applied every reasonable method for identifying suspicious orders. Plaintiff reserves the right to supplement or amend this answer as expert discovery commences.

ANSWER: In a good faith effort to meet its discovery obligations, consistent with the requirements set forth by Special Master Cohen in his Discovery Rulings 7 and 12, Plaintiff hereby identifies the orders identified in Bellwether Plaintiffs' prior responses as suspicious orders.

Further answering, Mallinckrodt has produced consolidated unusual order reports at MNK-T1_0007730452, MNK-T1_0007730468; MNK-T1_0001810733; MNK-T1_0002079926; and MNK-T1_ MNK-T1_0001810813. In addition, Mallinckrodt has produced peculiar order spreadsheets (*see* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 32 Ex. A); unusual order reports (*see* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 32 Ex. B); and DEA suspicious order reports (*see* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 32 Exs. C & D). Plaintiff contends that many of the orders identified in these documents were suspicious and were improperly shipped by Mallinckrodt.

Mallinckrodt has also identified 24 orders prior to 2009 that it determined were suspicious and were not shipped. *See* MNK-T1_0007026342, MNK-T1_000269049, MNK-T1_000301983, MNK-T1_0006805898, MNK-T1_0004268059, MNK-T1_0004267998, MNK-T1_000301986, MNK-T1_000277496, MNK-T1_000274675, MNK-T1_000269046, MNK-

T1_000275736, MNK-T1_000275748, MNK-T1_000562325, MNK-T1_000259231, MNK-T1_0000259220, MNK-T1_0000475208, MNK-T1_0000475126, MNK-T1_0000296226, MNK-T1_0008590891, MNK-T1_0007202509, MNK-T1_0002363592, MNK-T1_0006442328, MNK-T1_0007730869, and MNK-T1_0007202115. In addition to these orders, Mallinckrodt has identified thousands of orders that have the same or similar identifying information as the above orders but were nevertheless shipped. *See* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 32 at 53 and MNK-T1_0008592409. Plaintiff contends that many of these orders were suspicious and were improperly shipped by Mallinckrodt.

Plaintiff has also identified numerous documents and obtained testimony demonstrating that Mallinckrodt failed to adequately review and scrutinize suspicious orders prior to shipping them, including the deposition transcripts, deposition exhibits and custodial files of: Karen Harper, Eileen Spaulding, John Gillies, Bill Ratliff, Victor Borelli, Steven Becker, Ginger Collier, Kate Muhlenkamp, Lisa Cardetti, James Rausch, Cathy Stewart, George Saffold, and Tiffany Rowley-Kilper. The custodial files for the above individuals also contain additional documents supporting Plaintiff's claims regarding the lack of adequate due diligence.

In addition, Mallinckrodt has identified the following prescribers and "other individuals" that it believes engaged in "inappropriate prescribing practices or other illegal acts concerning the diversion of Opioids into the illegal supply chain": Dr. Adolp Harper, Dr. Brian Heim, Dr. Ronald Celeste, Dr. Michael Tricaso, Dr. Gregory Gerber, Louis Eppinger, Patricia Arnold, Anthony H. Perry, Elizabeth Davis, James Byrge, Judy Barrows, Brittany Glass, Patricia Laughman, Adria Harper, and Tequilla Berry. *See* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 21 at 21. A review of Mallinckrodt's documents indicates that these individuals obtained Mallinckrodt products, and that many of these individuals were well known to Mallinckrodt prior to their arrests were on Mallinckrodt "target" lists of high-

prescribing doctors that it actively solicited to prescribe their products. *See, e.g.*, MNK-T1_0002159629, MNK-T1_0002282670, MNK-T1_0004814570, MNK-T1_0002719188, MNK-T1_0007068789.

Plaintiff reserves the right to supplement or amend its response as expert discovery commences, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Dated: March 4, 2019

Respectfully submitted,

By: */s/ Linda Singer*_____

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